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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99N-2607

Dear Sir or Madam:

We are writing to comment on FDA's proposed estimate of annual reporting burden associated with the collection of information imposed on hearing aid manufacturers under 21 C.F.R. 810.420(c). 64 Fed. Reg. 46395 (August 25, 1999). Specifically, we wish to comment upon "the accuracy of FDA's estimate of the burdens of the proposed collection of information." 64 Fed. Reg. 46395. Under section 801.420, hearing aid manufacturers are required to provide a User Instructional Brochure ("UIB") for distribution to users and customers considering use of hearing aids, and to any health care professional or prospective user who requests one in writing. FDA's regulations require that the UIB contain data useful to the user in selecting, fitting, and checking the performance of a hearing aid, as well as technical data about the device, instructions for use, warnings, a notice regarding the requirement for (or procedure for waiver of) a medical evaluation, and a disclosure if the hearing aid is rebuilt or reused.

Under the Paperwork Reduction Act, 44 U.S.C. 3506(c)(2)(A), FDA is required to publish for comment in the *Federal Register* a notice of proposed extensions of existing information collection requirements. The notice is to include a description of likely respondents and the proposed frequency of response to regulatory requirements, 44 U.S.C. 3507(a)(1)(D)(ii)(IV), and an estimate of the burden resulting from the collection of information in response to regulatory requirements, 3507(a)(1)(D)(ii)(V). Under the regulations implementing the Act, an agency's estimate must represent, to the extent practicable, "the average burden of collection" for the whole of the respondents affected. 5 C.F.R. 1320.8(a)(4).

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The Hearing Industries Association (HIA) submitted information on the burden of collection for hearing aid manufacturers in August of 1998, in response to FDA's June 30, 1998, notice announcing the opportunity to comment on the proposed collection of information. The information provided to the agency was based on the responses to a survey of HIA members. While FDA incorporated into its August 1999, notice numbers that more closely reflect the average burden of collection as determined by the HIA our survey, the agency did not increase the average number of staff hours per brochure to 136. Instead, FDA used the number 102, the source of which is unclear. The number 136 came from a survey, albeit a limited one, of members of the affected group. FDA has not disclosed the basis for asserting the number 102 and disregarding the number HIA ascertained by means of its survey of the affected group. Accordingly, FDA's numbers still underestimate the total burden imposed on hearing aid manufacturers by the regulations in 21 C.F.R. 801.420(c).

FDA's current estimate is that 801.420(c) will impose on 40 hearing aid manufacturers 97,920 hours of work per year; the number jumps to 130,560 if HIA's survey result number of 136 hours per response is used. This works out to an average of 2448 (if FDA's number is used) or 3264 (if the survey-based number is used) additional hours per year per manufacturer. This is a very substantial burden that is not justified. One of the reasons the number is so high is that the information required by 801.420(c) is so specific that hearing aid manufacturers often draft a new UIB for each small permutation of a device. Some models offer different features and can be customized for individual users. Thus, many models have more than one brochure. On average, hearing aid manufacturers produced six more brochures than models of hearing aids.

Accordingly, before the burden imposed by this regulatory requirement is allowed to continue, under 5 C.F.R. 1320.8(a)(4), FDA should revisit its assumptions and provide a more realistic calculation of the burden the UIB requirement imposes on hearing aid manufacturers.

Sincerely,

Carole M. Rogin
President

Cc: HIA Member Firms